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Fast-Track Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	Repackaging of drugs by PACE facilities
Date this document prepared	10/9/15

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

As required by Chapter 505 of the 2015 Acts of the Assembly, the Board of Pharmacy is promulgating regulations "relating to the training, packaging, labeling, and recordkeeping" for repackaging of prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) site licensed by the Department of Social Services and overseen by the Department of Medical Assistance Services. Repackaging requirements are identical to those previously adopted for a similar purpose at community services boards and behavioral health authorities.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CSB = community services boards
BHA = behavioral health authority
PACE = program of all-inclusive care for the elderly

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On September 29, 2015, the Board of Pharmacy amended 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
...
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

The legal authority for the Board of Pharmacy to promulgate the proposed regulation is found in Chapter 505 of the 2015 Acts of the Assembly (HB1733):

§ 54.1-3420.2. Delivery of prescription drug order.

...E. Prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) site licensed by the Department of Social Services pursuant to § 63.2-1701 and overseen by the Department of Medical Assistance Services in accordance with §

32.1-330.3 upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the site on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by the PACE site for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

The authority to promulgate regulations to establish criteria for repackaging by PACE sites is mandatory.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the planned regulatory action is to comply with a legislative mandate to promulgate regulations for PACE sites to receive, store, retain, and repackage prescription drug orders dispensed to a patient for the purpose of assisting a client with self-administration of the drug.

House Bill 1733 (2015) was introduced to address a problem for the PACE program in handling the unique prescription needs of its patient population. The legislation does two things:

1) It authorizes the PACE sites to retain prescription medications for elderly patients, who may need assistance or monitoring of self-administration or who may not be capable of self-administering.
2) It authorizes PACE personnel, who hold appropriate licensure or who have passed a training course approved by the Board of Pharmacy, to repackage a portion of a patient's medication to assist that patient with self-administration and compliance with dosage instructions.

Because of the urgent need for the change in law and for regulations to implement those changes, the Board of Pharmacy is promulgating amendments by a fast-track action. Regulations addressing storage, repackaging, recordkeeping and training of persons who handle drugs will ensure that client or patient needs are being met while protecting the security and integrity of the drugs and the health and safety of the client and general population.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

This action will not be controversial as repackaging authorization is needed as soon as possible. Cindy Williams with Riverside Health Systems, which has a number of PACE facilities, gave public comment at the meeting on September 29th, urging the Board to adopt the draft regulations recommended by the Regulation Committee. The Board adopted the recommendation without change.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

Regulations promulgated pursuant to the legislative mandate set forth requirements for PACE sites to possess, repackage and deliver or administer drugs and for a program to train non-pharmacists in repackaging. Amendments add PACE to requirements for other facilities (CSB's and BHA's) that have similar authority. They include requirements for labeling, storage, recordkeeping, destruction and other requirements for repackaging in those facilities that do not have a pharmacy, persons authorized to repackage, and information to clients about repackaged drugs. There are also curricula and instructional criteria for approval of repackaging training programs and for expiration and renewal of program approval.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The advantage to the public is assurance that a facility has followed appropriate procedures in the storing, retaining, and repackaging of dispensed prescription drug orders for the purpose of assisting elderly clients with self-administration. Without proper training, there are concerns about drug safety and security and about improper dispensed of prescriptions that enable a person to remain in a community-based program. There are no disadvantages.
2) The advantage to the Commonwealth is facilitation of a community program that assists elderly clients with health-related needs.
3) Since there was no statutory authority for emergency regulations, the Board is promulgating a fast-track action to authorize repackaging as soon as possible.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods consistent with health and safety of the elderly patients served by PACE.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. All notifications will be done electronically. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	The entities that would be affected by the ability to use non-licensed persons trained to repackage would be PACE programs licensed by DSS

Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are currently 8 PACE provider organizations in Virginia, serving a total of 12 licensed sites. They are associated with health system such as Centra and Sentara and are not considered small businesses.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	If PACE facilities use a training program already developed by Virginia Association of Community Services Boards and approved by the Board of Pharmacy, there would be no costs for program approval. There would be minimal costs for recordkeeping and administration of a repackaging program.
Beneficial impact the regulation is designed to produce.	Compliance with statute to develop regulations for repackaging of drugs at PACE facilities. The ability of community-based programs to repackage prescription drugs for clients without employing or contracting with a pharmacist could potentially reduce costs for their operations.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no less intrusive or less costly alternatives. The PACE programs will follow the same requirements already established for CSB's and BHA's which have proved to be beneficial in providing services to a certain population of citizens who need assistance with self-administration of medications.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

Adoption and approval regulations to implement provisions of HB1733 will have a positive impact on the family and family stability as elderly clients of PACE programs will have adequate access to medications necessary to keep them safe and stable in the community.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

685	Sets out definitions for controlled substances registration by facilities such as PACE	Adds a definition for PACE consistent with the description in the Code.
700	Sets out the requirements for supervision in facilities that hold a controlled substance registration	Subsection C is amended to expand access to controlled substances to persons who have completed repackaging training for a PACE site. A second amendment adds repackaging of prescription drug orders at a PACE site is within the scope of practice of a pharmacy technician, if approved by the supervising pharmacist.
725	Sets out all requirements for repackaging in a PACE site	Subsection A define "repackaging" for the purposes of this section as removing a drug from a container already dispensed and labeled by a pharmacy or medical practitioner authorized to dispense, for a particular client, and placing it in a container designed for a person to be able to repackage his own dispensed prescription medications to assist with self-administration and compliance with dosage instructions. **PACE sites are added to current regulations for CSB's and BHA's.** *The purpose of defining repackaging as it applies to the activity by an unlicensed person is to ensure that it is not confused with repackaging performed in a pharmacy and to clarify that training in "repackaging" as defined in this section does not qualify an individual to repackage drugs in other settings and for other purposes.* The regulations also stipulate that such repackaging does not

		include the preparation of a patient-specific label which includes drug name, strength, or directions for use or any other process restricted to a pharmacist or pharmacy technician under the direct supervision of a pharmacist. *Preparation of such a label is an act restricted in law to a pharmacist, pharmacy technician under the direct supervision of a pharmacist, or physician licensed to dispense.* Subsection B specifies those persons who are authorized to repackage, including a pharmacist, pharmacy technician, nurse, or another person who has successfully completed a board-approved training program for repackaging of prescription drug orders as authorized by statute. If a PACE site uses non-licensed persons who have received specific repackaging training, it must maintain documentation of completion of an approved training program for at least one year from date of termination of employment or cessation of repackaging activities. *Inspectors for the board will check on whether the PACE site has followed regulations on storage, recordkeeping, etc. and whether persons who are authorized to do so are repackaging the drugs dispensed to clients of the facility.* Subsection C sets out the requirements for repackaging. **PACE is added to <u>current requirements</u> for CSB's and BHA's.** They include: 1. The repackaging of a dispensed prescription drug order pursuant to § 54.1-3420.2. 2. The repackaging of dispensed prescription drugs shall be restricted to solid oral dosage forms and a maximum of a 14-day supply of drugs. 3. The drug container used for repackaging pursuant to this section shall bear a label containing the client's first and last name, and name and 24-hour contact information for the facility. 4. A clean, well-closed container that assists the client with self-administration shall be used when multiple doses of a repackaged drug are provided to the client at one time. 5. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier. *All requirements are intended to improve compliance with dosage directions, minimize risks, and improve the safety of the drugs being dispensed. Drugs will typically be repackaged into re-usable medication planning packaging (plastic containers with separate compartments for days of the week and times of day that consumers often purchase to repackage their own medications).* Subsection D requires that at the time a repackaged drug is initially given to a client, and upon any subsequent change in the medication order, the client must be provided written information about the name and strength of the drug and the directions for use. Such written information shall have been

		prepared by a pharmacy or by a nurse at the PACE site. *This written information is intended to provide the client, client's family, or any other health care provider in an emergency with information about drug names, strengths, dosage directions, and dispensing pharmacy name since this information resides on the dispensed pharmacy container with labeling which will in many cases have been retained at the PACE site.* Subsection E sets out the requirements for retention, storage and destruction of repackaged drugs. It provides that: 1. Any portion of a client's prescription drug order not placed into a container intended to assist with self-administration may be either given to the client or retained by the PACE site for subsequent repackaging. If retained by PACE, the remaining portion shall be stored within the board-approved drug storage location in the original labeled container, and shall only be used for the client for whom the drug was originally dispensed. *Drugs maintained at a PACE site have been prescribed and dispensed by a pharmacy for a specific patient or client. The drugs must be kept in a secure location and not given out to other clients.* 2. Any portion of a prescription drug order remaining at the PACE site that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the PACE site shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client. *To ensure the drug's safety and integrity, rules are written for handling of expired drugs or discontinued medications.* Subsection F sets out the rules for keeping records, as follows: 1. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following: a. Date of repackaging; b. Name of client; c. Prescription number of the originally dispensed prescription drug order; d. Pharmacy name; e. Drug name and strength; f. Quantity of drug repackaged; and g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container. *Recordkeeping is important to be able to track what drugs have been dispensed and given to clients in case of errors, recalls or other need for information.* 2. A record of destruction shall be made and maintained for

		one year for any prescription drug orders destroyed by the PACE site and shall include the following: a. Date of destruction: b. Name of client; c. Prescription number of the originally dispensed prescription drug order; d. Drug name and strength; e. Quantity of drug destroyed; and f. Initials of the person performing the destruction.
726	Establishes the criteria for a training program in repackaging.	**PACE programs are added to the current regulations for CSB's and BHA's.** Subsection A provides that any person wishing to apply for approval of a repackaging training program must submit the $50 application fee and an application on a form approved by the board and must meet the criteria established in this section. The application must name a program director who is responsible for compliance with this section. *An application is necessary in order for the board to have basic information on which to base its approval and to have a contact person accountable for the program and its content. Since the CSB training program is already approved by the Board, it is likely that PACE programs will use that program and not incur the cost of developing its own.* Subsection B sets out the requirements for the curriculum of a training program to include instruction in current laws and regulations applicable to a PACE for the purpose of assisting a client with self-administration and in the following repackaging tasks: 1. Selection of an appropriate container; 2. Proper preparation of a container in accordance with instructions for administration; 3. Selection of the drug; 4. Counting of the drug; 5. Repackaging of the drug within the selected container; 6. Maintenance of records; 7. Proper storage of drugs; 8. Translation of medical abbreviations; 9. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage administration; 10. Reporting and recording the client's failure to take medication; 11. Identification, separation and removal of expired or discontinued drugs; and 12. Prevention and reporting of repackaging errors. *The curriculum for the program is intending to minimally prepare a person to accomplish this limited repackaging with safety and accuracy. The person must be able to read a prescription label, correctly remove the drugs and appropriately package the dosages in compliance packaging or*

		boxes. The person responsible for repackaging must also know what to do if the client has not been compliant with medications, if there are changes in orders, and if an error has occurred. Subsection C establishes requirements for instructors and a program director. Instructors for the program shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; or (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked in any jurisdiction in the United States. The program director shall maintain a list of instructors for the program. *The only persons qualified to teach someone to accurately and safely repackage drugs are persons who have had training and experience in repackaging and are deemed to be competent in those tasks.* Subsection D sets general requirements for the program to include: 1. The length of the program shall be sufficient to prepare a program participant to competently perform repackaging consistent with §54.1-3420.2 and 18 VAC 110-20-725. *The board did not stipulate the number of hours for a program since it may vary depending on the experience of the trainee, the number of persons being trained and other factors.* 2. The program shall include a post-training assessment to demonstrate the knowledge and skills necessary for repackaging with safety and accuracy. *While there is no standardized test of competency, the program must assure that there is a post-test assessment.* 3. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by a PACE site or by the board. 4. The program shall maintain records of training completion by persons authorized to repackage in accordance with §54.1-3420.2. Records shall be retained for two years from date of completion of training or termination of the program. *A certificate of completion is necessary for the person to be able to demonstrate training to employers and to representatives of the board.* 5. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, name of institution or business if applicable, address, program content, length of program, or location of records. *A report of substantive changes is necessary in order for the board to maintain an accurate record of training programs.* Subsection E provides that a repackaging training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program must submit the renewal application, renewal fee, and a self-

		evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew will be based on documentation of continued compliance with the criteria set forth in this section. *Requirements for renewal of a training program are similar to those for a pharmacy technician training program, which must also be approved by the board.*
727	Provides criteria for pharmacists repackaging for clients of a PACE site as an alternative to repackaging by a person trained for that purpose.	A pharmacist repackaging for a PACE site must ensure compliance packaging that complies with the requirements of 18 VAC 110-20-340 B and 18 VAC 110-20-725, subsections G, H, and J. A primary provider pharmacy may also provide this service in compliance with the provisions of 18 VAC 110-20-535.